



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM**

**DATE:** April 2, 2020

**SUBJECT:** Efficacy Review for MDF-200 Part B,  
EPA Reg. No. 91889-2  
DP Barcode: 457017  
E-submission No. 48070

**FROM:** Thao Pham  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510P)

**TO:** Steven Snyderman, PM 33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

**APPLICANT:** Span-World LLC.

*Thao Pham*

**FORMULATION FROM LABEL (Part B):**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Hydrogen peroxide .....	7.9%
<u>Other ingredients:</u> .....	<u>92.1%</u>
Total.....	100.0%

**FORMULATION FROM LABEL (EPA Reg. No. 91889-1, Part A):**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Alkyl (50% C14, 10% C16, 40% C12) Dimethyl benzyl ammonium chloride .....	3.2%
<u>Other ingredients:</u> .....	<u>96.8%</u>
Total.....	100.0%

## **I BACKGROUND**

**Product Description (as packaged, as applied):** 2 part product – combine equal parts A and B, then apply as a trigger spray

**Submission type:** Label Amendment

**Currently registered efficacy claim(s):** Disinfectant (bactericidal, fungicidal, virucidal)

**Requested action(s):** Addition of emerging viral pathogen claim, citing data from EPA Reg. Nos. 80346-1 and 80346-2.

**Documents considered in this review:**

- Cover letter from applicant/agent to EPA dated March 17, 2020
- Terms of Registration (not dated)
- Proposed label dated March 17, 2020
- Data matrix (EPA form 8570-35) dated March 16, 2020
- Efficacy review for DP354407 and DP354408.

## II CONCLUSION

MRID	Emerging virus claim	Organism(s)	Type of Virus (family)	Surface Type	Application Method(s) and/or Dilution	Contact Time	Soil load	Data support label claims?
46821202	<ul style="list-style-type: none"> <li>• Enveloped viruses</li> <li>• Large nonenveloped viruses</li> </ul>	Influenza A (ATCC VR-544)	Enveloped Virus	Hard nonporous surfaces	Part A & B Combined; Ready to use trigger spray	10 minutes	5%	No, enveloped viruses cannot be used to support EVP claims
46821203	<ul style="list-style-type: none"> <li>• Enveloped viruses</li> <li>• Large nonenveloped viruses</li> </ul>	Influenza B (ATCC VR-823)	Enveloped Virus	Hard nonporous surfaces	Part A & B Combined; Ready to use trigger spray	10 minutes	5%	No, enveloped viruses cannot be used to support EVP claims
47448401 47448402	<ul style="list-style-type: none"> <li>• Enveloped viruses</li> <li>• Large nonenveloped viruses</li> </ul>	Feline calicivirus (Strain F-9; ATCC VR-782)	Small, Nonenveloped Virus	Hard nonporous surfaces	Part A & B Combined; Ready to use trigger spray	10 minutes	5%	Yes

### III LABEL COMMENTS (3/17/20)

The proposed label claims that the product, MDF-200 Part B (when combined with equal parts Part A), qualifies for the following emerging viral pathogens claim:

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	<b>One of the following:</b> Influenza A (ATCC VR-544) Influenza B (ATCC VR-823) Feline calicivirus (Strain F-9; ATCC VR-782)
Large Nonenveloped virus	<b>One of the following:</b> Influenza A (ATCC VR-544) Influenza B (ATCC VR-823) Feline calicivirus (Strain F-9; ATCC VR-782)

These claims are **partially acceptable**.

**Please revise the emerging viral pathogens statement on page 10 exactly as follows:**

“This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

This product (when combined with equal parts MDF-200 Part A) meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Feline calicivirus (Strain F-9; ATCC VR-782)
Large, non-enveloped virus	Feline calicivirus (Strain F-9; ATCC VR-782)

Acceptable claim language:

**“MDF-200 Part A & Part B combination** has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard, **non-porous surfaces**. Therefore, **MDF-200 Part A & Part B combination** can be used against **[name of emerging virus]** when used in accordance with the directions for use against **Feline calicivirus (Strain F-9; ATCC VR-782)** on **hard, non-porous surfaces**. Refer to the **[CDC or OIE]** website at **[pathogen-specific website address]** for additional information.

**[Name of illness/outbreak]** is caused by **[name of emerging virus]**. **MDF-200 Part A & Part B combination** kills similar viruses and therefore can be used against **[name of emerging virus]** when used in accordance with the directions for use against **Feline calicivirus (Strain F-**

**9; ATCC VR-782) on *hard, non-porous surfaces*. Refer to the [CDC or OIE] website at [website address] for additional information.”**

**In addition, please make the following changes to the Terms of Registration. Note that there should not be any specific mention of SARS-CoV-2 or COVID 19:**

The Terms of Registration should be dated, have the product name and registration number, and include the following:

“Per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’, [Company Name] agrees to the following terms of registration:

This product (when combined with equal parts MDF-200 Part A) meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Feline calicivirus (Strain F-9; ATCC VR-782)
Large, non-enveloped virus	Feline calicivirus (Strain F-9; ATCC VR-782)

1. The statements shall be made only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.
2. Statements shall adhere to one or both of the following formats:
  - **“MDF-200 Part A & Part B combination** has demonstrated effectiveness against viruses similar to [name of emerging virus] on **hard, non-porous surfaces**. Therefore, **MDF-200 Part A & Part B combination** can be used against [name of emerging virus] when used in accordance with the directions for use against **Feline calicivirus (Strain F-9; ATCC VR-782) on hard, non-porous surfaces**. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.
  - **[Name of illness/outbreak] is caused by [name of emerging virus]. MDF-200 Part A & Part B combination** kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against **Feline calicivirus (Strain F-9; ATCC VR-782) on hard, non-porous surfaces**. Refer to the [CDC or OIE] website at [website address] for additional information.”
3. The registrant may begin communicating these statement(s) upon notification on the CDC or OIE website identified under Section V of the Guidance of an outbreak of an emerging **large non-enveloped and/or enveloped** viral pathogen. The registrant shall cease and remove all such non-label communications intended for consumers no later than 24 months after the original notification of the outbreak on the CDC or OIE website, unless the agency provides

guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

4. The registrant agrees that paragraphs 1 through 3 above shall become immediately void and ineffective if registration for use against [name of supporting virus(es)] is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category would also be grounds for voiding paragraphs 1 through 3.”

Please make the following additional changes to the proposed label the next time an amendment is submitted to the agency:

1. On page 1 of the label, remove “Decontaminant” as this term is reserved for products tested against *B. anthracis*.